Plan says a drug is not medically necessary	
Action:	Explanation:
1. Client requests an official decision (a "Coverage Determination") from the plan.  Exception: If 72 hours (three days) is too long for client to wait for an answer, client may request an Expedited Coverage Determination. See #3 below.	<ul> <li>Client may get a Coverage Determination more quickly if a written request is submitted.</li> <li>Client may have help in asking for the Coverage Determination. The helper may be anyone, including the client's friend, family member, doctor, or volunteer, and is called the Authorized Representative. If someone has been appointed to make decisions for the client, such as a guardian or "conservator," that person is the client's Authorized Representative.</li> </ul>
2. Plan must tell client and doctor what the Coverage Determination is within 72 hours (three calendar days) after receiving request.  Exception: Timeframes for Expedited Coverage Determinations are in #3 below.	<ul> <li>♦ If the Coverage Determination denies coverage of a prescribed medication, the plan must give the client written notice within 72 hours, telling the reason for the denial and how to appeal the decision. (See sample denial letter in Appendix A.)</li> <li>♦ If the plan fails to provide written notice within these timeframes, it must start the next level of appeal by sending the request for the Coverage Determination to an Independent Review Entity (IRE) within 24 hours.</li> </ul>

Plan says a drug is not medically necessary	
Action:	Explanation:
3. Client may request an Expedited Coverage Determination if the client, doctor or both believe that waiting 72 hours for a Coverage Determination might seriously jeopardize the client's health, life or ability to regain maximum function.	<ul> <li>If the doctor makes the request or supports the client's request for an Expedited Coverage Determination, the plan will expedite its response. In these cases, the plan must notify both the client and the doctor of the decision. If the client's prescribing doctor does not request or support the request, the plan will decide if the client qualifies for an Expedited Coverage Determination.</li> <li>If an Expedited Coverage Determination is granted, the plan MUST respond as soon as possible (taking into account client's health condition), but no later than within 24 hours. The plan may initially respond by telephone. The plan must send the client a written Expedited Coverage Determination within three calendar days of any verbal notification within the first 24 hours. The notice must explain the plans' reasons for the</li> </ul>
	decision, and, if the decision is not in the client's favor, provide information on how to appeal.
	♦ If the plan fails to respond within these timeframes, the plan must start the next level of appeal by sending the request to the Independent Review Entity.

- ♦ Prescribed medication is not in the plan's formulary, or
- ♦ Client can't afford the prescribed drug or the cost-sharing amounts of the drug, or
- ♦ Plan removed the drug from the formulary, or changed the drug's cost-sharing amount (plan must give client 60 days written notice, and may not make changes in Open Enrollment or plan's first 60 days), or
- ♦ Client didn't go through "step therapy" protocol (or action by the plan to reduce costs, such as: substitutions; dosage limitations; requiring prior plan approval, etc.)

Action:	Explanation:
Client may talk to prescribing doctor to see if there is an equivalent medication in the plan's formulary that the doctor believes would work as well and is willing to prescribe.	
If prescribing doctor believes client needs the denied medication, client may request a Formulary Exception from the plan.	<ul> <li>Client may have help in asking for a Formulary Exception. The helper may be anyone, including the client's friend, family member, doctor, or volunteer, and is called the Authorized Representative. If someone has been appointed to make decisions for the client, such as a guardian or "conservator," that person is the client's Authorized Representative.</li> </ul>

NOTE: Information taken from Health Assistance Partnership's "Help! I Couldn't Get My Prescription Filled." Online. Internet. 22 Dec. 2005. Available: www.healthassistancepartnership.org.

- ♦ Prescribed medication is not in the plan's formulary, or
- ♦ Client can't afford the prescribed drug or the cost-sharing amounts of the drug, or
- ♦ Plan removed the drug from the formulary, or changed the drug's cost-sharing amount (plan must give client 60 days written notice, and may not make changes in Open Enrollment or plan's first 60 days), or
- ♦ Client didn't go through "step therapy" protocol (or action by the plan to reduce costs, such as: substitutions; dosage limitations; requiring prior plan approval, etc.)

Action:	Explanation:
2. (continued)	<ul> <li>Formulary Exceptions may be requested for coverage of a non-formulary drug, or to get a lower cost-sharing amount on a covered drug. The plan may prohibit Formulary Exceptions to lower cost-sharing amounts for high cost or "unique" drugs (genomic / biotech products).</li> <li>The plan must have a "Formulary Exception Process" which includes the factors considered in evaluating these requests, and a procedure for the plan to review relevant medical evidence on the safety of the requested medication. This process should be spelled out in the plan policy.</li> <li>The prescribing doctor will have to contact the plan to explain why the prescribed medication is medically necessary. The doctor will likely need to provide the plan a written statement with the following information:</li> </ul>

- ♦ Prescribed medication is not in the plan's formulary, or
- ♦ Client can't afford the prescribed drug or the cost-sharing amounts of the drug, or
- ♦ Plan removed the drug from the formulary, or changed the drug's cost-sharing amount (plan must give client 60 days written notice, and may not make changes in Open Enrollment or plan's first 60 days), or
- ♦ Client didn't go through "step therapy" protocol (or action by the plan to reduce costs, such as: substitutions; dosage limitations; requiring prior plan approval, etc.)

Action:	Explanation:
2. (continued)	<ul> <li>Verifying that no other drug in the formulary would be as effective, or that all other drugs in the formulary for treating the client's condition give the client bad side effects.</li> <li>Providing additional supporting medical documentation, including evidence of the safety of the requested medication.</li> </ul>
3. If a Formulary Exception is granted, the plan may charge the client what it charges for non-preferred and brand name drugs in the formulary.	◆ The client will not be allowed to get the cost-sharing lowered to the amount for generic drugs, if the plan has a separate tier of cost-sharing solely for generic drugs. The client will not be allowed to request another Formulary Exception in order to get lower cost-sharing on the drug.

- ♦ Prescribed medication is not in the plan's formulary, or
- ♦ Client can't afford the prescribed drug or the cost-sharing amounts of the drug, or
- ♦ Plan removed the drug from the formulary, or changed the drug's cost-sharing amount (plan must give client 60 days written notice, and may not make changes in Open Enrollment or plan's first 60 days), or
- ♦ Client didn't go through "step therapy" protocol (or action by the plan to reduce costs, such as: substitutions; dosage limitations; requiring prior plan approval, etc.)

Action:	Explanation:
3. (continued)	◆ The Formulary Exception lasts for the rest of the plan year. If the client renews enrollment in the same plan for the following year, the plan can decide whether or not to continue allowing the Formulary Exception in the new plan year. If the Formulary Exception ends, the client may have to re-request the Formulary Exception.

The client went to a non-network (or out-of-network) pharmacy:	
Action:	Explanation:
1. The client may go to a non- network pharmacy only if he or she could not reasonably have been expected to get to a participating in-network pharmacy.  Exception: Residents of long- term care institutions as defined by federal regulation are generally prohibited from filling their prescriptions at non- network pharmacies.	Clients are not allowed to regularly fill prescriptions at a non-network pharmacy. Plans are allowed to have rules to limit clients' use of non-network pharmacies.

The drug prescribed is prohibited by law from coverage under any Medicare plan.	
Action:	Explanation:
The client may wish to consider an enhanced supplemental Medicare prescription drug plan, which provides supplemental coverage of any drugs prohibited by law from coverage under Medicare.	
The client may wish to consider other payment methods for these drugs.	<ul> <li>◆ Other payment methods may include, but are not limited to:         <ul> <li>Out-of-pocket</li> <li>State pharmacy assistance program</li> <li>Other insurer (such as employment-based, VA, TriCare, etc.).</li> <li>Medicaid (Note: For Medicaid recipients, DSHS will pay for non-Medicare drugs covered under Medicaid before 2006.)</li> </ul> </li> </ul>

Plan's Coverage Determination or Formulary Exception decision is not in client's favor.	
Action:	Explanation:
The client may appeal a decision by asking for a Redetermination.      Exception: Client or doctor may request an Expedited Redetermination, if the Coverage Determination or the Formulary Exception Request was expedited. See #3 below.	◆ Client does this by writing to the plan within 60 days from the written notice denying the Coverage Determination or Formulary Exception, at the address indicated on the denial. Client may write to the plan after 60 days, if the client has a good reason why he or she was unable to submit the request within 60 days.
2. The plan will make a decision within seven (7) days.  Exception: Timeframes for Expedited Redetermination Requests are explained in #3 below.	◆ If the decision is in the client's favor, the decision will also be implemented within this time.

Plan's Coverage Determination or Formulary Exception decision is not in client's favor.	
Action:	Explanation:
Client or doctor may request an Expedited Redetermination.	<ul> <li>If the doctor requests that the Redetermination be expedited, the plan must expedite it. In this case, the plan must notify both the client and the doctor of the decision.</li> <li>Expedited Redeterminations must be decided by the plan in no more than 72 hours.</li> <li>Client may submit evidence and legal arguments to the plan, either in</li> </ul>
4. If the client does not agree with the Redetermination decision, the client can appeal by requesting a Reconsideration.	<ul> <li>Person or in writing.</li> <li>Reconsiderations must be requested within 60 days of the date on the plan's notice of Redetermination decision.</li> </ul>
	<ul> <li>Reconsideration requests are addressed by Independent Review Entities (IREs) that contract with CMS.</li> <li>The IRE must ask the prescribing physician for an opinion on the appeal, and include a written account of the doctor's input in the record.</li> </ul>

Plan's Coverage Determination or Formulary Exception decision is not in client's favor.	
Action:	Explanation:
4. (continued)	◆ The IRE will send the client a notice of Reconsideration when it has reached its decision.
5. If the client disagrees with the Reconsideration decision, the client may ask for a hearing before an administrative law judge (ALJ).	<ul> <li>The hearing must be requested within 60 days of the date on the notice from the IRE about the Reconsideration decision.</li> <li>The cost of the drug that is the subject of appeal must be at least \$100 for the client to get an ALJ hearing.</li> </ul>
6. If the client disagrees with the decision of the ALJ, the client may ask the Medicare Appeals Council to review that decision.	

Plan's Coverage Determination or Formulary Exception decision is not in client's favor.	
Action:	Explanation:
7. If the client disagrees with the Medicare Appeals Council decision, the client may appeal the case to federal court if the amount in controversy is at least \$1050.	

Approved OMB #0938-0976

## [LOGO]

#### **Notice of Denial of Medicare Prescription Drug Coverage**

Date:	
Enrollee's name:	Member ID number:
We have denied coverage of the following prescription drug(s) that you or your physician requested:	
We denied this request because:	

## What If I Don't Agree With This Decision?

You have the right to appeal. If you want to appeal, you must request your appeal within 60 calendar days after the date of this notice. We can give you more time if you have a good reason for missing the deadline. You have the right to ask us for an exception if you believe you need a drug that is not on our list of covered drugs (formulary) or believe you should get a drug at a lower cost-sharing amount. You can also ask for an exception to utilization management tools, such as a dose restriction or step therapy requirement. Your physician must provide a statement to support your exception request.

## Who May Request an Appeal?

You or someone you name to act for	
representative) may request an appe	•
friend, advocate, attorney, doctor, or s	someone else to act for you.
Others may already be authorized und	der State law to act for you.
You can call us at: ()	to learn how to name
your appointed representative. If you	have a hearing or speech
impairment, please call us at TTY (	
Form No. CMC 10116	

Form No. CMS-10146

#### IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

For more information about your appeal rights, call us or see your Evidence of Coverage.

below:

# There Are Two Kinds of Appeals You Can Request

Expedited (72 hours) - You can request an expedited (fast) appeal if you or your doctor believe that your health could be seriously harmed by waiting up to 7 days for a decision. If your request to expedite is granted, we must give you a decision no later than 72 hours after we get your appeal.

- If the doctor who prescribed the drug(s) asks for an expedited appeal for you, or supports you in asking for one, and the doctor indicates that waiting for 7 days could seriously harm your health, we will automatically expedite your appeal.
- If you ask for an expedited appeal without support from a doctor, we will decide if your health requires an expedited appeal. If we do not give you an expedited appeal, we will decide your appeal within 7 days.
- Your appeal will not be expedited if you've already received the drug you are appealing.

#### **How Do I Request an Appeal?**

For an Expedited Appeal: You or your appointed representative should contact us by telephone or fax at the numbers below:

Pnone: ( )	
Fax: ( )	
For a Standard Appeal: You or	
your appointed representative	
should mail or deliver your written	
appeal request to the address(es)	

What Happens Next? If you appeal, we will review your case and give you a decision. If any of the prescription drugs you requested are still denied, you can request an independent review of your case by a reviewer outside of your Medicare Drug Plan. If you disagree with that decision, you will have the right to further appeal. You will be notified of your appeal rights if this happens.

#### **Contact Information:**

If you need information or help, call

**Standard (7 days) -** You can request a standard appeal. We must give you a decision no later than 7 days after we get your appeal.

# What Do I Include with My Appeal Request?

You should include your name, address, Member ID number, the reasons for appealing, and any evidence you wish to attach. If your appeal relates to a decision by us to deny a drug that is not on our formulary, your prescribing physician must indicate that all the drugs on any tier of our formulary would not be as effective to treat your condition as the requested offformulary drug or would harm your health.

us at:

Toll Free:

TTY:

#### Other Resources To Help You:

Medicare Rights Center

Toll Free: 1-888-HMO-9050

TTY:

Elder Care Locator

Toll Free: 1-800-677-1116

1-800-MEDICARE (1-800-633-

4227)

TTY: 1-877-486-2048